MAY 0 8 2014

510(k) Summary

GENERAL INFORMATION

5.1 Type of Submission

Special 510(k) Submission

Submission date: 12/02/2013

5.2 Submitter

Name: eResearchTechnology GmbH

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Germany

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5.3 Establishment Registration Number

3008505660

5.4 Common Name or Classification Name

Diagnostic Spirometer (CFR 868.1840, Product Code BZG)

5.5 Trade Name

Asthma Monitor AM3 / AM3 BT / AM3 GSM

5.6 Device Classification

This is a Class II device

5.7 Classification Panel

73 Anesthesiology Part 868
Code BZG

5.8 Reason for Premarket Notification

Device modification to an existing device regarding "The New 510(k) Paradigm"
- Additional data transfer to Database by GSM;
- Li-Ion battery – is used as energy type

5.9 Legally predicate marketed device

Asthma Monitor AM3/AM3 BT
K092890 Code BZG

5.10 Predicate Device Company

eResearchTechnology GmbH (device was formally listed by Carefusion Germany 234 GmbH)

5.11 Device Description

The Asthma Monitor AM3 GSM is a medical device (peak flow meter with symptom diary) providing following characteristics:

- Handheld device
- Battery operation
- Storing capacity of 1200 measurements
- Storing capacity of 400 sets of questionnaires (max. 20 questions each)
- Measurement Parameters: PEF and FEV1
- Accuracy Flow: ± 5% or ± 20 l/min
- Accuracy Volume: ± 3% or ± 0.05 liter
- Data transmission to computer/database via USB, Bluetooth, GSM and Serial (RS232)
- Flow sensor (single patient use)
- Mouthpiece (single patient use)

5.12 Intended Use Statement

The Asthma Monitor AM3/AM3 BT/AM3 GSM is an electronic measurement device to monitor the lung function (determination of the respiratory flows and volume) with high reproducibility wherever and whenever there is a need of. The AM3 measures the flow during expiration serving for the calculation of further parameters as FEV1.

The AM3 is used to monitor the respiratory status of adult human beings in the areas of asthma, chronic obstructive pulmonary disorder and in areas like occupational medicine, clinical trials and disease management.

The patient is informed of the results by numeric values for the selected parameters (e.g. PEF, FEV1). Furthermore, a visual control unit, displayed in the form of traffic lights, allows an immediate indication of the measurement based on criteria defined by the patient's physician.

The device saves the results of a measurement (always with date and time) automatically in an internal database. In addition, questionnaire functionality can be called up by the use of a software package (AMOS) to record e.g. the "Quality of Life" status. When enabled, the AM3 can be programmed with a couple of questions, where the patient can then select from a couple of different answers. This information is also stored in the internal database and can be transmitted for evaluation to a standard PC using the software package AMOS.

The AM3 is designed to replace an ordinary peak flow meter, diary and pencil by a single system. Easy handling, sturdy and handy design allow the Asthma Monitor AM3 to be used in healthcare, clinical and home use environments/settings.

5.13 Required Components

AM3 / AM3 BT /AM3 GSM measurement device
Accessories
User Manual

5.14 Summary Table of Comparison

a) Comparison with Asthma Monitor AM3/AM3 BT with 510(k) K092890

	Asthma Monitor AM3/AM3 BT (K092890)	**Asthma Monitor AM3 GSM**
Indications for Use	The Asthma Monitor AM3 / *AM3 BT from Cardinal Health* is an electronic measurement device to monitor the lung function	The Asthma Monitor AM3/AM3 BT/AM3 GSM is an electronic measurement device to monitor the lung function (determination

	(determination of the respiratory flows and volume) with high reproducibility wherever and whenever is a need of. The AM3 / *AM3 BT* measures the flow during expiration serving for the calculation of further parameters as FEV1. The AM3 / *AM3 BT* is used to monitor the respiratory status of human beings in the areas asthma, chronic obstructive pulmonary disorder and in areas like occupational medicine, clinical trials and disease management. The patient is informed of the results by numeric values for selected parameters (e.g. PEF, FEV1). Furthermore a visual control unit, displayed as a kind of traffic lights, allows an immediate indication of the measurement based on criteria defined by the patient's physician. The device saves the results of a measurement (always with date and time) automatically in an internal database. *The memory capacity is designed to store up to 400 measurements.* In addition, a questionnaire functionality can be called up by the use of a software package (AMOS) to record e.g. the "Quality of Life" status. When enabled, the AM3 / *AM3 BT* can be programmed with a couple of questions, where the patient can select then from a couple of different answers. This information is also stored in the internal database and can be transmitted for evaluation to a standard PC using the software package AMOS. The AM3 / *AM3 BT* is designed to replace ordinary peak flow meter, diary and pencil by a single system. Easy handling, sturdy and handy design allow the AM3 / *AM3 BT* being used almost everywhere: at work, at home, in school, for experts opinion, research or clinical trial purposes and in occupational medicine.	of the respiratory flows and volume) with high reproducibility wherever and whenever is a need of. The AM3 measures the flow during expiration serving far the calculation of further parameters as FEV1. The AM3 is used to monitor the respiratory status of human adult beings in the areas asthma, chronic obstructive pulmonary disorder and in areas like occupational medicine, clinical trials and disease management. The patient is informed of the results by numeric values for selected parameters (e.g. PEF, FEV1). Furthermore a visual control unit, displayed as a kind of traffic lights, allows an immediate indication of the measurement based on criteria defined by the patient's physician. The device saves the results of a measurement (always with date and time) automatically in an internal database. In addition, a questionnaire functionality can be called up by the use of a software package (AMOS) to record e.g. the "Quality of Life" status. When enabled, the AM3 can be programmed with a couple of questions, where the patient can select then from a couple of different answers. This information is also stored in the internal database and can be transmitted for evaluation to a standard PC using the software package AMOS. The AM3 is designed to replace ordinary peak flow meter, diary and pencil by a single system. Easy handling, sturdy and handy design allow the Asthma Monitor AM3 being used in healthcare, clinical and home use environments/settings, for expert opinion, research or clinical trial purposes and in occupational medicine.

		→ **Besides minor wording changes the Intended Use is identical to K092890 (see italic text in Intended Use of to K092890)**
Patient population	The Asthma Monitor can be used for patients from 4 years on and older.	**identical**
Dimensions (housing)	Length x Width x Height: 112*82*37 mm Weight: 167 g (batteries included)	Length x Width x Height: 112*82*37 mm Weight: 120 g (batteries included)
Display	LCD module Size: 54,0 x 33,5 mm 255 x 160 dots	**Identical**
Key-panel	Foil Key-panel (4 keys): - ESC (on/off) - UP-ARROW - DOWN-ARROW - OK	**identical**
Integrated mouthpiece (material)	Polysterol 454C	**identical**
Single Use mouthpiece (material)	Bormed RG835 MO	**identical**
Performance (measurements)	Parameters: PEF FEV1	**identical**
Interface	Serial RS 232 & USB & Blue-tooth	Serial RS 232 & USB & Blue-tooth & GSM
Energy type	3 x 1,5 (Micro AAA)	LI-ION Polymer battery 3.7 V, 1700 mAh
Operating Require-ments	PC software AMOS	**identical**
Bluetooth	WML-C46 (Mitsumi)	**identical**

interface		
GSM Interface	none	Sierra Wireless WISMO288

Discussion of the table above:

The insignificant difference to the AM3/AM3 BT (K092890) is:

- **GSM** – is used for wireless data transfer to a Database as an additional possibility besides the serial, USB and BlueTooth interface communication. GSM (Global System for Mobile communications) is an open, digital cellular technology used for transmitting mobile voice and data services. The in-built GSM module is used instead of an external cell phone paired to the AM3 BT to transmit the data to a database.
- The device performance is not affected by adding the GSM function, as the data transfer is offline and will not take place when a measurement is active or a questionnaire is performed.
- As the data transfer is offline to the measurement or questionnaire functionality and all data is stored in a nonvolatile memory. The availability of reception to the GSM is not critical, as the data transfer could be done at any time without any influence to the device functionality.
- The wireless transfer is based on the use of the GSM module Sierra Wireless WISMO288. The GSM module uses techniques to guarantee the integrity of the transferred data. Latency and throughput is part of the GSM module implementation. The use of the qualified GSM module ensures that the latency and throughput requirements were met.
- Minor modifications of the software concerning the GSM module are verified. The software requirements and design specifications submitted, include requirements and specifications of the entire device. Based on the recommendations of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" only verification reports related to the modifications which caused the need for a Special 510(k) are submitted.
- The Applicable EMC and telecommunications standards and regulations, including device emissions that may cause EMI with other equipment are fulfilled.
- **Li-Ion battery** – is used as energy type. The battery has to be charged by a power supply. The Li-Ion battery and the power supply fulfil the common standards and were implemented and tested for safe and effective use.

5.15 Summary of Device Testing

The following practices were followed and monitored for development of the Asthma Monitor AM3 with the GSM data transmission:

- The GSM data transmission for the above device was developed in accordance with the eResearchTechnology development standard operating procedures.

- The risk analysis method used to assess the impact of Asthma Monitor AM3 / AM3 BT with the additional GSM data transmission was a Failure Modes and Effects Analysis (FMEA).
- Safety test procedures demonstrate satisfaction of all safety requirements and mitigation of all identified hazards.
- The EMC testing was performed according EN 60601-1-2.
- The GSM module was tested according to R&TTE and FCC guidelines.
- The software was developed according to the IEC 62304 Standard.

5.16 Conclusions

Based on the above, eResearchTechnology concludes that the Asthma Monitor AM3 with the "GSM" data transmission module does not raise new questions of safety and effectiveness and is as safe and as effective for its intended use, and performs at least as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 8, 2014

eResearchTechnology GmbH
Richard Miller
Vice President, Quality Management
1818 Market Street, Suite 1000
Philadelphia, PA 19103

Re: K133722
Trade/Device Name: Asthma Monitor AM3 GSM
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: April 07, 2014
Received: April 08, 2014

Dear Mr. Miller:

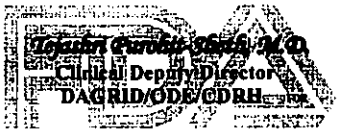
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133722

Device Name: AM3
AM3 BT
AM3 GSM

Indications for Use:

The Asthma Monitor AM3/AM3 BT/AM3 GSM is an electronic measurement device to monitor the lung function (determination of the respiratory flows and volume) with high reproducibility wherever and whenever there is a need of. The AM3 measures the flow during expiration serving for the calculation of further parameters as FEV1.

The AM3 is used to monitor the respiratory status of adult human beings in the areas of asthma, chronic obstructive pulmonary disorder and in areas like occupational medicine, clinical trials and disease management.

The patient is informed of the results by numeric values for the selected parameters (e.g. PEF, FEV1). Furthermore, a visual control unit, displayed in the form of traffic lights, allows an immediate indication of the measurement based on criteria defined by the patient's physician.

The device saves the results of a measurement (always with date and time) automatically in an internal database. In addition, questionnaire functionality can be called up by the use of a software package (AMOS) to record e.g. the "Quality of Life" status. When enabled, the AM3 can be programmed with a couple of questions, where the patient can then select from a couple of different answers. This information is also stored in the internal database and can be transmitted for evaluation to a standard PC using the software package AMOS.

The AM3 is designed to replace an ordinary peak flow meter, diary and pencil by a single system. Easy handling, sturdy and handy design allow the Asthma Monitor AM3 to be used in healthcare, clinical and home use environments/settings.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anya C. Harry -S
2014.05.08 06:07:44 -04'00'